THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TMDA

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

CELON LABORATORIES PRIVATE LIMITED, TELANGANA, INDIA

PUBLIC GMP INSPECTION REPORT

March, 2025

General information about the company

Manufacturers details	
Name of manufacturer	Celon Laboratories Private Limited
Corporate address of manufacturer	Plot No: 3, Aleap Industrial Estate, Gajularamaram Village, Quthbullapur (M), Medchal-Malkajgiri, Telangana, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	i. Oncology Block ii. General Injectables Block
Inspection details	
Date of inspection	13th - 14th June, 2024
Type of inspection	Pre-Registration GMP inspection
Introduction	
General information about the company and site	The manufacturing facility was located at ALEAP Industrial Estate, Gajularamaram, Medchal Malkajgiri District- 500090, Telangana State, India. In 2007 Celon Labs Pvt Ltd in Plot 2 was established and enhanced by the addition of Plot 3 as separate site. In 2023 Plot No. 2 was upgraded.
History	The facility had a valid GMP certificate No. 137960/TS/2024 issued by Drug Control Administration, Telangana on 10/05/2024 for manufacturing of oncology products. The facility also holds the GMP certificate No. 115370/TS/2023 issued by local NMRA on 28/02/2021 which is valid up to 27/01/2026 for

	manufacturing of general injectables. The site was inspected and approved by other regulatory authorities such as Cambodia, NDA-Rwanda, PPB - Kenya, NDA - Uganda, Ivory Coast, Iran, Russia, Philippines and Sri Lanka.
Brief report of the activities undertaken	
Areas inspected	Areas inspected include external surroundings, Quality Control (QC) laboratory, utilities that including the water treatment plant, HVAC system, compressed air, and pure steam generation system, and the review of documentation In particular, the following systems were inspected: • Pharmaceutical Quality • Production System • Facilities and Equipment System • Laboratory Control System • Material System • Packaging and labelling System
Restrictions	The GMP inspection was restricted to oncology sterile injections and general injectables
Out of scope	Any lines whose products are not applied for registration in Tanzania.
Production lines inspected by TMDA	The inspection focused on manufacturing lines for; i. Oncology sterile injections in the form of liquid vials and lyophilized vials, oncology tablets, and capsules. ii. General injectables in the form of liquid vials, lyophilized vials, liquid ampoules, and prefilled syringes
Abbreviations	**Meaning**
GMP	Good Manufacturing Practices
cGMP	Current Good Manufacturing Practices

CNC	Controlled non-classified area
AHU	Air Handling Unit

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had adequate number of technical staffs with necessary qualifications and experience to carry out their tasks. Job descriptions were provided to staff including key personnel to define individual responsibilities in-line with the recruitment profile. Key positions were occupied by full-time, qualified, and experienced personnel. Head of Quality Assurance (QA), Production and Quality Control (QC) were independent from each other as evidenced in their job description, appointment letters and organogram.

Personnel met during inspection demonstrated awareness on the principles of cGMP which proved that they have been imparted with basic principles of cGMP training and on job training pertaining to their area of work. The SOP and schedule for GMP training and selected records for some technical staff were reviewed and found to meet the requirements.

The procedure for medical checkup was in place. All personnel were subjected to pre-employment and on job medical examination as per procedure. Pre-employment health check was done for new employees and all other personnel were checked annually. In addition, personnel involved in visual inspection activities were qualified and listed as visual inspectors according to the procedure.

2. Premises

a. Layout and Design

The facility was located, designed, constructed, adopted and maintained to suit the operations carried out. Interior surfaces (walls and floors) of storage and production areas were constructed with suitable materials that permit effective cleaning and sanitation. The layout of the facility allowed for the maintenance of major components from the service corridors. The entire manufacturing and warehouse areas of all blocks were designed for ventilation and filtered air was supplied through air handling units installed. All areas were provided with adequate working space for working and logical placement of equipment and materials to avoid mix us and cross contamination. The buildings were provided with change rooms with proper gowning instructions.

The premise was designed in such a way that it allowed for unidirectional flow of materials and that personnel movement and material movement were also segregated to minimize the possibility of contamination.

b. Sanitation and Hygiene

Sanitation and hygiene were observed in all areas including the surrounding, premises, equipment and personnel. In addition, the premises were situated in an environment which presented minimal risk of contamination of raw materials and finished products.

Additional change was provided for personnel entering production areas. Personnel were provided with appropriate protective garments when entering the production, filling and packaging areas. Hand washing and sanitization facilities were provided in the change rooms. The production rooms were cleaned and well maintained according to the laid down procedure.

There were written procedures for cleaning of manufacturing areas and equipment. All areas were cleaned daily as per respective SOP. During inspection, cleaning validation protocols and reports were reviewed and found satisfactory.

3. Production

Dispensing of raw material was done by qualified personnel according to the approved procedures. It was verified that, all measures were taken to prevent contamination of the opened containers, the materials and protect the operator during dispensing procedures. Dispensing of active pharmaceutical ingredient (API) was performed under well-functioning Reverse Laminar Flow (RLAF). In addition, separate entry of materials through pass box and personnel through change room were provided. Personnel change room was equipped with step over bench, cabinet for keeping garments, caps and shoes covers, hand sanitizer and dustbins.
From common dispensing area materials were transferred to the production area through LAF dynamic pass box.

Oncology block

a. Production Line I (Oral solid dosage in the form of tablets production lines:

This line was dedicated for production of Oral solid dosage in form of tablets and capsules. Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production.

b. Production Line II (small volume parenteral in form of ampoules, vials and prefilled syringes)

This line was dedicated for Production of injectable oncology products. Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production. In process Quality control (IPQC) was conducted and parameters monitored were recorded. Proper line clearance which was performed before production of each batch.

General Injectable block

Production Line I (small volume parenteral in form of ampoules, vials and prefilled syringes)

This line was dedicated for production of small volume parenteral in form of ampoules, vials and prefilled syringes. Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production. In process Quality control (IPQC) was conducted and parameters monitored were recorded. Proper line clearance was performed before production of each batch.

Generally, in all production blocks measures to prevent cross contamination and mix ups were in place and use of status labelling of materials and products, use of validated clean procedures, use of segregated production cubicles, adequate pressure differential was maintained in corridors with respect to manufacturing cubicles, monitoring of pressure differentials, temperature and relative humidity, use of primary, secondary and tertiary gowning procedures before going to production areas, instituting campaign manufacturing, use of sealed double polyethylene bags and HDPE containers for storage of dispensed and in process materials with proper labelling and identification, use of dedicated sampling and dispensing booth for APIs, excipients and packaging materials, proper segregation of packaging lines and performing line clearance before starting manufacturing and packaging operations were in place. Samples were received, registered and distributed to analysts through Laboratory Information Management System (LIMS). Testing was conducted as per the specifications using validated analytical procedures

4. Quality Control

The laboratory was equipped with analytical instruments for quantitative and qualitative testing of all raw materials, excipients, packaging materials and finished goods. All equipment and instruments were coded, qualified, calibrated and labeled.

Samples were properly managed and stored depending on the storage conditions requirements. Analytical tests were performed according to the validated in-house analytical methods and/or pharmacopoeia methods based on specifications. OOS and OOT results investigated and managed as per procedure which was reviewed and accepted, records were well maintained

The facility had reference standards for use in analytical testing. The primary reference standards used for qualification of secondary working standards were verified and found properly managed and easily traceable.

5. Equipment

The facility was provided with modern equipment for production and quality control which were generally located, installed, designed, constructed, and maintained to fit the purposes of the operations to be carried out. The equipment was adequately calibrated and labeled.

a. Qualification

Major manufacturing equipment was subjected to designed qualification, installation qualification, operational qualification and performance qualification as evidenced in the reviewed qualification protocol and report of vial Filling and stoppering machine.

Protocol showed that different parameters were qualified including output at set speed, filling and stoppering efficiency and fill volume verification. Review of the report: revealed to be within the criteria set in the protocol, the report revealed all parameters monitored to be within the criteria set in the protocol.

b. Preventive maintenance

The preventive maintenance of equipment was implemented as per SOP. It was described that monthly, quarterly, half-yearly, and yearly maintenance frequency was implemented. Master preventive maintenance schedules for the year 2024 was reviewed. A spot check of preventive maintenance for vial washing machine in the General Block was conducted and found to be performed as per the schedule.

c. Cleaning and sanitation

Sanitation and hygiene were observed in all areas including the surrounding, premises, equipment and personnel. Compounding, filtration and filling vessels were cleaned by CIP and sterilized by SIP systems as per the validated procedure in place.

6. Purified water System

The facility had designed, installed, qualified, validated, operated and maintained Water Treatment Plant (WTP) for generation and distribution of Purified Water System (PW).

There was separate Water Treatment plant for each block. The source of raw water was bore well. Raw water was treated to generate portable water and then to passed to reverse osmosis system followed by EDI. The purification system was also comprised of UV lights whereby light intensity was monitored and recorded. The generated purified water was stored in SS316L storage tanks and distributed through SS pipes under UV sterilization and continuous loop system circulation at a temperature above 80°C.Sampling points were identified/labelled. The system was cleaned, sanitized and maintained as per schedule and records were verified. The system had real time monitoring devices for pressure, flow rate, conductivity and TOC readings. Moreover, the system was validated and proved to consistently produce water of desired specifications.

7. Heating, Ventilation and Air Conditioning

Manufacturing activities were carried out in containment facilities under highly closed environment to avoid contamination, cross contamination and for the safety of operators. Separate AHUs were provided for oncology and general blocks.

Each production block had dedicated HVAC system which were qualified. Installed AHUs were capable of supplying filtered air into various manufacturing rooms and laboratory. AHU's were clearly labelled to indicate the supplied rooms and direction of airflow. The HVAC systems were designed to suit the area supplied. Maintenance and servicing of AHUs were done by full time employed and qualified persons according to SOP. Magnehelic pressure gauges were installed across filters of AHUs to measure pressure differential and assurance of filter integrity.

8. Document Review

The review of documents proved that the company had a good documentation infrastructure as documents were well designed and prepared as per GMP requirements. The documents were approved, signed and dated by the appropriate responsible persons and distributed with care, Records were kept up to date and documents reviews were done in timely manner.

Part 3: Conclusion

Based on compliance report on inspection findings the facility **Celon Laboratories Private Limited, Plot No: 3, Aleap Industrial Estate, Gajularamaram Village, Quthbullapur (M), Medchal-Malkajgiri, Telangana, India** complies with the minimum requirements of the TMDA Guidelines for Good Manufacturing Practices (GMP) Inspection of Human Medicinal Products Manufacturing Facilities April, 2023 for the manufacturing of oncology products inform of liquid vials, lyophilized vials, tablets and capsules and general injectable products inform of liquid vials, lyophilized vials, liquid ampoules and pre-filled syringes.

This TRIP will remain valid for three (3) years from the date of approval for GMP compliance provided that the outcome of any inspection conducted during this period is positive

Part 4: References

1. TMDA (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition,
2. WHO Technical Report Series (TRS) related to GMP;
3. TMDA Good Manufacturing Practices Manual *and SOPs*, Tanzania Medicines and Drugs Authority, Dar-es-Salaam, Tanzania.
4. Tanzania Medicines and Medical Devices Act, Cap 219.